BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :		(11) International Publication Number: WO 92/20388
A61M 5/20	A1	(43) International Publication Date: 26 November 1992 (26.11.92)

(21) International Application Number: PCT/GB92/00846

(22) International Filing Date: 11 May 1992 (11.05.92)

(30) Priority data:

9110340.8	13 May 1991 (13.05.91)	GB
9117561.2	14 August 1991 (14.08.91)	GB

(71) Applicant *(for all designated States except US)*: MEDIMECH INTERNATIONAL LIMITED [GB/GB]; 34-35 Riverside, Sir Thomas Longley Road, Frindsbury, Rochester, Kent ME2 4DP (GB).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)* : WILMOT, John, Glyndwr [GB/GB]; 44 Rectory Lane North, Leybourne, Nr. West Malling, Kent ME19 5RA (GB).

(74) Agent: BARKER, BRETTELL & DUNCAN; 138 Hagley Road, Edgbaston, Birmingham B16 9PW (GB).

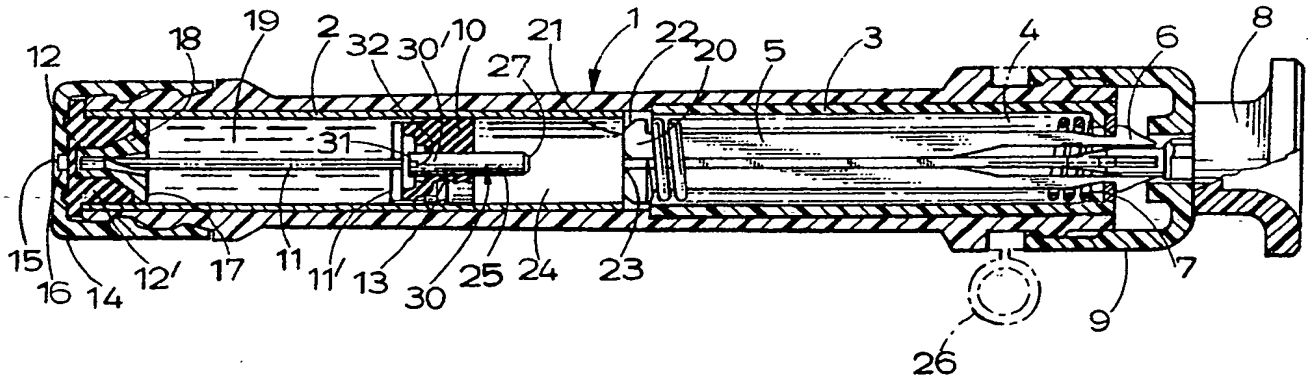
(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB, GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), NO, SE (European patent), US.

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: AUTOMATIC INJECTORS



(57) Abstract

An automatic injector is disclosed having a body (1), a medicament chamber (19) defined in the body, a needle (11) held in a sheathed position within the body, releasable drive means (4) which when released drives the needle from its sheathed position to an unsheathed position, and expulsion means (5, 10) for discharging the medicament through the needle (11), characterised in that seal means (12) is provided at the forward end of the medicament chamber (19), and in that the expulsion means (5, 10) has an expulsion element (10) and the needle (11) is movable forwards in a seal-breaking phase of movement relative to the expulsion element (10) upon activation of the injector so as to pierce the seal means (12). Thus it is not the entire expulsion means (5, 10) plus needle (11) which moves forward to break the seal (12) and vent the medicament chamber (19), but only the needle (11).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FI	Finland	ML	Mali
AU	Australia	FR	France	MN	Mongolia
BB	Barbados	GA	Gabon	MR	Mauritania
BE	Belgium	GB	United Kingdom	MW	Malawi
BF	Burkina Faso	GN	Guinea	NL	Netherlands
BG	Bulgaria	GR	Greece	NO	Norway
BJ	Benin	HU	Hungary	PL	Poland
BR	Brazil	IE	Ireland	RO	Romania
CA	Canada	IT	Italy	RU	Russian Federation
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland			SN	Senegal
CI	Côte d'Ivoire	KR	Republic of Korea	SU	Soviet Union
CM	Cameroon	LI	Liechtenstein	TD	Chad
CS	Czechoslovakia	LK	Sri Lanka	TG	Togo
DE	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		
ES	Spain	MG	Madagascar		

AUTOMATIC INJECTORS

This invention relates to automatic injectors of the kind having a body, a medicament chamber defined in the body, a needle held in a sheathed position within the body, releasable drive means which when released drives the needle from its sheathed position to an unsheathed position, and expulsion means for discharging the medicament through the needle. Such injectors will hereinafter be referred to as being 'of the kind set forth'.

Automatic injectors of the kind set forth are known, for example from US 2 832 339 which shows an injector with a medicament chamber defined between the forward end of a sliding plunger, comprising the expulsion means, and the end of the body, the needle being housed in the medicament chamber in its sheathed position and being driven forward through a seal at the end of the body by the sliding plunger upon release of the drive means. In order to drive the needle forward the volume of the medicament chamber must be reduced.

The seal of US 2 832 339 is relatively thick. The drawings of US 2 832 339 show the medicament chamber full of liquid medicament, but this is not in fact true. In practice such arrangements where the volume of a liquid medicament chamber must be reduced in order to drive the needle forward some considerable way in order to break the seal invariably have a volume of air introduced into the medicament chamber during manufacture in order for the air to be compressed by the expulsion means initially so as to allow the needle to move forward and break the seal. This avoids the hydraulic lock which would otherwise occur if the

injector was really made in accordance with the drawings of US 2 832 339.

Injecting air into the human body can be very dangerous. Injecting an air bubble into muscle tissue is not usually too catastrophic since the air is usually simply absorbed by the tissue. However, if an air bubble is injected into an artery the resulting embolism can cause death. In battlefield conditions where automatic injectors such as that of US 2 832 339 find their main use the risk of injecting air is accepted in order to obtain a fast response to an immediate emergency, such as nerve gas attack or the user bleeding from a bullet wound. In less extreme emergencies the risk of injecting air would counsel against using automatic injectors.

It is an aim of the invention to alleviate at least some of the problems problems associated with automatic injectors of the kind set forth.

According to the invention we provide an automatic injector of the kind set forth having seal means at the forward end of the medicament chamber, and in which the expulsion means has an expulsion element and the needle is movable forwards in a seal-breaking phase of movement relative to the expulsion element upon activation of the injector so as to pierce the seal means.

Thus it is not the entire expulsion means plus needle which moves forward to break the seal and vent the medicament chamber.

Preferably the expulsion element has a relatively large cross-sectional area in comparison with that of the needle.

Preferably the seal-breaking phase is an initial phase of operation of the injector and during a subsequent expulsion phase the expulsion element and needle move forwards together as the medicament is forced out of the medicament chamber.

During the seal-breaking phase of movement of the needle a component of the expulsion means may move rearwardly so as to tend to increase the volume of the medicament chamber.

Preferably the movement of the needle relative to the expulsion element in the seal-breaking phase causes little or substantially no decrease in volume of the medicament chamber.

The expulsion component may have an expulsion member movable relative to the expulsion element and engagable with the needle.

The expulsion component may have second seal means which, when the needle is in its sheathed position, contacts a portion of the expulsion member, or of the needle, or a needle-carrying member, which is outside of the medicament chamber, said portion being moved forwards relative to the seal means during said seal-breaking phase of movement so as to be introduced into the medicament chamber. Said portion preferably has a cross-section which is not substantially greater than that of the more forward portions of the needle.

The expulsion member may be spaced from the rear end of the needle when the needle is in its sheathed position.

The expulsion member preferably has a projecting portion which projects rearwardly beyond the seal means when the needle is in its sheathed position. The projection portion is preferably driven forwards relative to the expulsion element during the seal-breaking phase.

The drive means may urge the needle, or the needle-carrying member, forwards automatically upon its release, preferably before also contacting and moving the expulsion element.

There is preferably an inertial acceleration space between the drive means and the expulsion member, needle, or needle-carrying member (most preferably the projecting portion if it is provided) such that the drive means acquires momentum before striking the expulsion member, needle, or needle-carrying member, so that the movement of the needle during the seal-breaking phase is faster than in the expulsion phase.

An embodiment of the invention will now be described by way of example only, with reference to the accompanying Figure which is a longitudinal cross section through an automatic injector in accordance with the invention.

The injector comprises a body 1 of injection-moulded polystyrene containing a barrel liner 2 of F.E.P. 160 and a spring casing 3 of polystyrene. A stainless steel coil compression

spring 4 is in the initial condition of the injector held in the compressed position, as shown in the drawing, by a collet 5 made in two halves having at their tail ends detent teeth 6 engaging a latch ring 7 seated in the end of the spring casing 3. A safety pin 8 of moulded nylon normally keeps the teeth 6 apart but when it is withdrawn they can be urged together to release the collet 5 by a short movement of an end cap 9.

This spring-restraining and release mechanism is known and is substantially the same as that disclosed in our European Patent Specification No. 0 361 668.

In the initial, storage, condition of the injector a rubber piston 10 is slidably and sealing received in the liner 2 at a position about two-thirds of the way along the liner. An injection needle 11 having a needle disc 11' is slidably housed in the forward end of the liner 2. A drive pin 30' is slidably and sealing mounted in a central bore 13 of the piston 10.

The rear end of the needle 11 abuts against the drive pin 30 (which is a separate component). The drive pin 30 has a front face 31 which is provided with a slot 32. The needle 11 may have a degree of axial 'play' and may move away from the pin 30 slightly.

In the condition shown, the tip of the needle 11 stops just short of a diaphragm seal 12 formed in a bush 12' which is held in the end of the barrel liner 2 by an end cap 14. The end cap 14 also has a thin membrane or skin 15 covering the end of a hole 16 for the needle.

The tip of the needle 11 is received in a guide 17 of HD polyethylene shaped as shown, with its outside fitting into the bush 12' and its inside a good sliding fit on the needle. At its inner end the guide has a convergent conical portion 18 which helps to lead the needle into the bore of the guide during assembly of the injector. The guide 17 may also have a thin membrane across its front.

The space between the piston 10 and the seal 12 contains the liquid medicament and forms a medicament chamber 19 which is in communication with an open hole in the needle provided at the rear end of the needle. The slot 32 ensures that the liquid medicament can still enter the rear end of the needle even when the needle is in engagement with the pin 30. Alternatively or additionally the side wall of the needle 11 may have a liquid entry hole.

The forward ends 20 of the fingers of the collet 5 are in the position shown disposed at the entry to the liner 2 and have a flat transverse piston-engaging face 21, an outer chamfer 22, and an inner chamfer 23. An air space 24 is provided between the ends 20 of the collet and the piston 10. The air space extends for about a third of the length of the liner 2.

The drive pin 30 extends rearwardly beyond the piston 10 and has a projection portion 25 which projects into the air space 24.

The medicament chamber 19 is full, or substantially full, of liquid. There is no relatively large air space in the chamber 19: it really is full of liquid.

A further safety pull-ring 26 (shown in dotted outline) may be provided between the end cap 9 and a shoulder on the body 1 if desired.

When the pin 8 is removed, and the further safety ring 26 removed if it is provided, the user places the front end of the injector against his body and presses on the end cap 9. The teeth 6 are urged towards each other and clear the ring 7 which releases the spring 4. The collet 5 is driven forwards by the spring, is guided by its chamfers 22 to enter the liner 2, accelerates in the space 24 and acquires significant momentum before it hits the rear end of the pin 30. The liner 2 prevents the fingers of the collet from spreading out too much, and the chamfers 23 on the front ends 20 co-operate with a complementary chamfer 27 on the rear end of the projecting portion 25 as the collet hits the pin.

The pin 30 is jolted forwards relative to the piston 10, with the projecting portion 25 sliding forwards into sealing engagement with the bore 13. As it does this a portion of the pin 30' previously outside of the medicament chamber 19 is introduced into the chamber, and the front face 31 of the pin 30 urges the needle 11 forwards. The forward end of the needle 11 is driven through any seal that the guide 17 may have, through the seal 12, and through the skin 15 of the cap 14. As this is completed the faces 21 of the collet engage the rear of the piston 10 and drive the piston 10 and pin 30, forwards together, reducing the volume of the medicament chamber 19, expelling the medicament through the needle, and driving the needle into the user.

It will be appreciated that in the injector shown in the drawing the part of the pin 30' which is introduced into the medicament chamber is that part which is originally within the plunger 10. Thus no part of the pin 30' which is originally in the space 24 comes into contact with medicament. This can be advantageous in keeping the medicament sterile.

It will also be appreciated that since the medicament chamber 19 contains no air the injector is safer for use by inexperienced users since injecting into an artery no longer carries a high risk of creating an embolism. This enables our injector to be used in less immediately life threatening circumstances, for example diabetics may use the injector more safety.

Since the pin is of very much smaller cross-sectional area . then the piston 10 problems associated with hydraulic lock due to the incompressability of the medicament are very much reduced in comparison with the arrangement in which the needle is in fixed relationship with the piston 10 and the entire piston has to be driven forward to pierce the seal and release the pressure in the medicament chamber.

The pin may have the same cross-section as the needle 11 so that there is a minimum, or even substantially no, decrease in the volume of the medicament chamber before the end seal is broken. The embodiment described has pin 30 of slightly larger cross-section than the needle 11, and there will tend to be a very slight decrease in the volume of the medicament chamber before its seal is broken due to more of the wider pin 30 entering the medicament

chamber. However, this can be accommodated by the piston 10 sliding rearwardly slightly before the seal is broken (whilst at the same time the pin moves forwards).

This feature can even enable the pin to have a relatively large cross section since hydraulic lock can be avoided by the piston sliding rearwardly slightly into the air space 24.

The automatic injector described with reference to the drawing is especially compact axially since it has its needle in the medicament chamber, instead of being externally attached to the medicament chamber.

In an alternative embodiment the collet contacts the drive pin, or is closely spaced from it, when the injector is in its storage condition. It is not necessary for the collet to build up momentum before engaging the pin for the device to operate.

A further modification has the needle 11 and pin 30 joined together as a single component. Whilst this is theoretically possible it is not our preferred arrangement.

CLAIMS

1. An automatic injector having a body (1), a medicament chamber (19) defined in the body, a needle (11) held in a sheathed position within the body, releasable drive means (4) which when released drives the needle from its sheathed position to an unsheathed position, and expulsion means (5,10) for discharging the medicament through the needle (11), characterised in that seal means (12) is provided at the forward end of the medicament chamber (19), and in that the expulsion means (5,10) has an expulsion element (10) and the needle (11) is movable forwards in a seal-breaking phase of movement relative to the expulsion element (10) upon activation of the injector so as to pierce the seal means (12).

2. An injector according to claim 1 in which the expulsion element (10) has a drive member (11') which is a separate component from the needle (11) and is movable relative to the expulsion element (10) so as to engage the needle (11) in use and drive it forwards.

3. An injector according to claim 2 in which the drive member (11') has a continuous smooth outer surface which is in sliding and sealing contact with the expulsion element (10).

4. An injector according to claim 2 or 3 in which the rear end of the needle (11) and the front face of the drive member (11') make face-to-face contact during the seal breaking phase of movement.

5. An injector according to any preceding claim in which the needle (11) has a rear end region provided with an aperture for liquid medicament to enter the

needle, the aperture being exposed to medicament when the injector is in its unactuated storage state.

6. An injector according to any preceding claim in which the forward end of the needle (11) is received in and guided by a needle guide (17) provided at the forward end of the body (1).

7. An injector according to any preceding claim in which the movement of the needle (11) relative to the expulsion element (10) in the seal-breaking phase causes little or substantially no decrease in volume of the medicament chamber.

8. An injector according to any preceding claim in which the expulsion element (10) has second seal means which, when the needle (11) is in its sheathed position, contacts a portion of drive member (11') which is outside of the medicament chamber (19), said portion being moved forwards relative to the seal means during said seal-breaking phase of movement so as to be introduced into the medicament chamber (19).

9. An injector according to claim 8 in which said portion has a cross-section which is not substantially greater than that of the more forward portions of the needle (11).

10. An injector according to any one of claims 2 to 9 in which the drive member (11') has a projecting portion (25) which projects rearwardly beyond the seal means (12) when the needle is in its sheathed position.

11. An injector according to claim 10 in which the projecting portion (25) is driven forwards relative to

the expulsion element (10) during the seal-breaking phase.

12. An injector according to any one of claims 2 to 11 in which the drive means (4) urges the drive member (11') forwards automatically upon its release before also contacting and moving the expulsion element (10) forwards.

13. An injector according to any one of claims 2 to 12 in which an acceleration space (24) between the drive means and the needle (11), or drive member (11'), is such that the drive means (4) acquires momentum before striking the needle, or drive member, so that the movement of the needle during the seal-breaking phase is faster than in the expulsion phase.

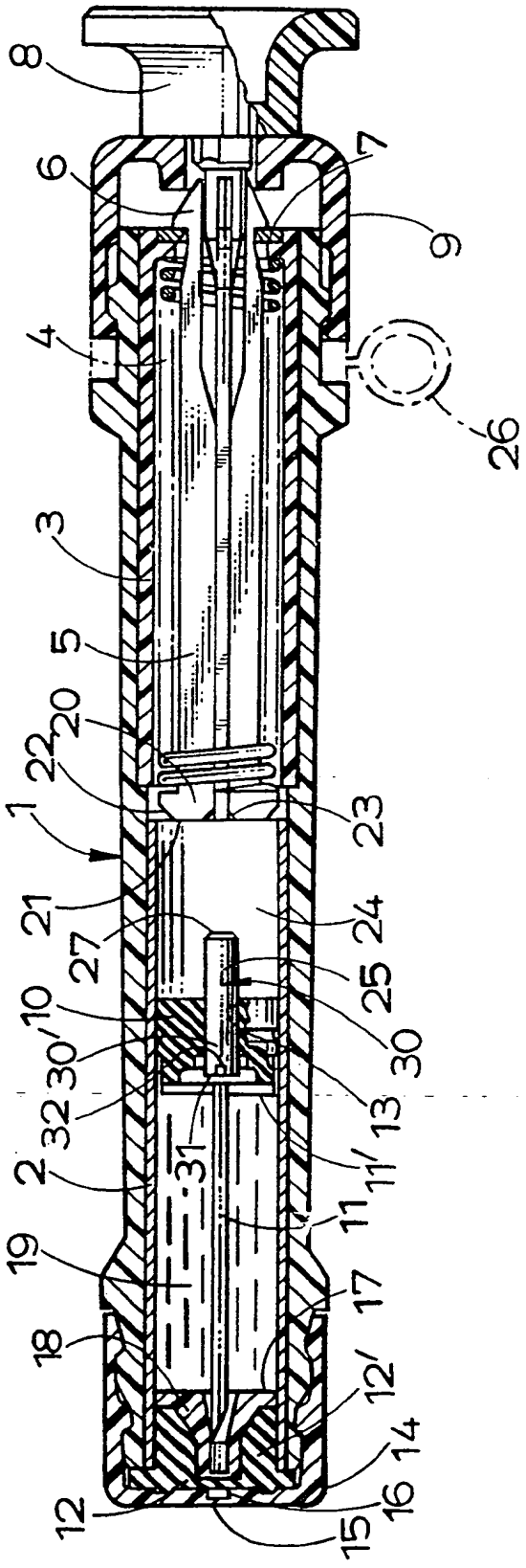
14. An injector according to any preceding claim in which the expulsion element (10) has a relatively large cross-sectional area in comparison with that of the needle (11).

15. An injector according to any preceding claim in which the seal-breaking phase is an initial phase of operation of the injector and during a subsequent expulsion phase the expulsion element (10) and needle (11) move forwards together as the medicament is forced out of the medicament chamber (19).

16. An injector according to any preceding claim in which during the seal-breaking phase of movement of the needle a component (10) of the expulsion means (5,10) moves rearwardly so as to tend to increase the volume of the medicament chamber (19).

17. An injector substantially as described and illustrated herein with reference to Figure 1 of the drawings.

1/1



INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 92/00846

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M5/20

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category[10]	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
Y	EP,A,0 361 668 (MEDIMECH LIMITED) 4 April 1990 cited in the application see column 4, line 49 - column 5, line 2 see column 5, line 58 - column 6, line 6; figure 3	1-16
Y	US,A,4 194 505 (SCHMITZ) 25 March 1980 see column 2, line 31 - line 55 see figures 3,6	1-16

[10] Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
16 SEPTEMBER 1992	30. 09. 92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	SEDY R.

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9200846 SA 60470

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 16/09/92 The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0361668	04-04-90	US-A- 5041088	20-08-91
US-A-4194505	25-03-80	None	